

FROM :

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UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Milton Hodosh
Serial No. : 09/072,504
Filed : May 4, 1998
For : **METHOD AND COMPOSITION FOR
PREVENTING TOOTH
HYPERSENSATIVITY WHEN USING
PASSEVE BLEACHING AGENTS**
Art Unit : 1614

#18
SUGGS
5/9/01

AFFIDAVIT OF ALEX HODOSH
UNDER 37 C.F.R. 1.608(b)

I, Alex Hodosh, declare as follows:

1. I am a doctor of dentistry with over ten years experience in the dentistry field and have extensive experience conducting dental bleaching treatments and other dental treatments which may cause hypersensitivity to the patient.

2. On a date prior to May 30, 1997 I witnessed a test conducted by Milton Hodosh. My signature bearing witness to the test appears at the bottom of Milton Hodosh's research notes, copy of which are attached hereto as Exhibit 1.

3. In the test Milton Hodosh combined KNO_3 with a bleaching compound available under the brand name "Karisma". The object of the test was to obtain a dental bleaching composition which prevented hypersensitivity.

4. The bleaching compound "Karisma" is manufactured by Confidential-Products Co. located at 385 S. Pierce Ave., Colorado Tech Center, Louisville, CO, 80027-3017. On information and belief "Karisma" contains carbamide peroxide as the active bleaching agent and a sticky matrix material that includes carboxypolymethylene.

5. The dental composition was administered to at least nine patients utilizing a dental tray which was adapted to hold the dental composition adjacent a person's tooth surfaces.

6. In each of the nine patients the dental bleaching composition effectively whitened patient's teeth and no hypersensitivity was reported.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

5-3-01
Date


Alex Hodosh

Research Notes

Combined 5%, 10%, 15%, saturated KNO_3 with Karmin Carbamide Peroxide in a glyceric base.) & C.V.S. Oral Bleaching antiseptics (also 10% Carbamide Peroxide in a glyceric vehicle with citric acid, Propylene Glycol, flavor, sodium stannate, & water). Karmin received from Dr. Brahma Sharma of Conf. Dental Products, Inc. [REDACTED]

Object - use in combination with peroxide yielding bleaching agent to prevent hypersensitivity seen with high frequencies when passive bleaching products are used especially in trays. [REDACTED]

Study from [REDACTED]

- Custom Trays made from impression models using the Munsivac - 5% KNO_3 added to Karmin in 9 subjects
10% added to C.V.S. in 6 subjects following the addition of 10 more% Carbamide Peroxide to the C.V.S. product - To see if could obtain more bleaching capability & overcome hypersensitivity produced from 20% Carbamide Peroxide.

In all cases no hypersensitivity resulted - the 15% & 20% [REDACTED] (Potassium nitrate) was unnecessary.

[REDACTED]

witness - [REDACTED]

Milton Adash

Sylvia Blazer
Gail Gibbs
Randy Gibbs
Judith Litchman
Barry Cohen
Fred Blazer
Belle David
Estelle Hodosh
Jean Gilbane

CD
above pts given Xarisma $\pm .57\% \text{KNO}_3$
added. no sensitivity encountered

Patients given CVS oral cleansing Antiseptic

Barry Cohen
Jean Gilbane
Barbara Shulkin
Jackie Hodosh
Judith Litchman
Michael Connors
W. Colomores